

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

JAMES WIERCIAK, on his own behalf,)	
and on behalf of a class of those similarly)	
situated,)	
)	
Plaintiffs,)	
)	
v.)	No. 1:14-CV-12
)	
THE INDIVIDUAL MEMBERS OF)	
THE MEDICAL LICENSING BOARD)	
OF INDIANA, in their official capacities,)	
)	CLASS ACTION COMPLAINT
Defendants.)	

Class Action Complaint for Declaratory and Injunctive Relief

Introduction

1. The Individual Members of the Medical Licensing Board of Indiana (“Board”) have adopted an emergency rule that was effective on December 15, 2013, which establishes standards and protocols for physicians who prescribe opioids for pain management treatment. Among other things, those who receive certain levels of opioids from physicians must now sign a treatment agreement that mandates drug monitoring testing at the beginning of their treatment and at least annually thereafter. There is no prohibition in the regulations, or in Indiana law, against law enforcement gaining access to the test results. Although the testing will be presumably performed by private entities, state-mandated drug testing represents a search that must be justified under the Fourth Amendment. The drug testing is not warranted under the Fourth Amendment and is unconstitutional. This portion of the emergency rule must therefore be enjoined.

Jurisdiction, venue, cause of action

2. This Court has jurisdiction of this matter pursuant to 28 U.S.C § 1331.
3. Venue is proper in this district pursuant to 28 U.S.C. § 1391.
4. Declaratory relief is authorized by 28 U.S.C. §§ 2201 and 2202.
5. This action is brought pursuant to 42 U.S.C. § 2000cc-2(a).

Parties

6. James Wierciak is an adult resident of Hamilton County, Indiana.
7. The Medical Licensing Board of the State of Indiana is an entity established by the State of Indiana, Indiana Code § 25-22.5-2-1, *et seq.*, that, among other things, licenses physicians and adopts rules “establishing standards for the competent practice of medicine” and “rules establishing standards and protocols for the prescribing of controlled substances.” Ind. Code § 25-22.5-2-7(a)(8), (a)(12). The Board consists of seven persons appointed by the Governor. Ind. Code § 25-22.5-2-1. The members are sued in their official capacities.

Class action allegations

8. James Wierciak brings this action on his own behalf and on behalf of a class of those similarly situated pursuant to Rule 23(a) and (b)(2) of the Federal Rules of Civil Procedure.
9. The class is defined as:

All patients, currently and in the future, subject to the Medical Licensing Board of Indiana’s Emergency Rule posted as LSA Document #13-495(E), or any subsequently promulgated rule containing similar terms regarding the requirement that patients consent to drug monitoring tests.

10. As defined, the class meets all the requirements of Rule 23(a) of the Federal Rules of Civil Procedure. Specifically:

- a. The class is so numerous that joinder of all members is impracticable. Although the exact size of the class is unknown at the current time, it is believed to be large. In 2009 retail pharmacies in the United States filled more than 256 million prescriptions for immediate and extended-release opioid pain relievers. Science Daily, *Access to Health Care Increases Prescription Opioids, Associated Abuse*,

<http://www.sciencedaily.com/releases/2013/11/131105081525.htm> (last accessed Jan. 3, 2014).

b. There are questions of law or fact common to the class, namely whether the emergency rule violates the Fourth Amendment.

c. The claims of the representative party are typical of those of the class.

d. The representative party will fairly and adequately represent the class.

11. The further requirements of Rule 23(b)(2) of the Federal Rules of Civil Procedure are met in that defendants have, at all time, acted and refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief and corresponding declaratory relief.

Legal background

12. Indiana Public Law 185, passed during the 2013 legislative session, created Indiana Code § 25-22.5-13, which required, among other things, that that the Medical Licensing Board of Indiana adopt an emergency rule prior to November 1, 2013 to establish standards and protocols for the prescribing of controlled substances. Ind. Code § 25-22.5-13(2)(a)(1).

13. In response to this legislative mandate the Board published an emergency rule on October 25, 2013, that is LSA Document #13-495(E). The emergency rule is attached to this Complaint.

12. The emergency rule “established standards and protocols for physicians in the prescribing of controlled substances for pain management treatment,” *id.* at Section 1, and “establish requirements” that must be complied with by physicians and patients “concerning the use of opioids for chronic pain management.” *Id.* at Section 3(a).

13. Physicians must comply with the emergency rule as a condition of continued licensure.

14. The specific substances regulated by the rule are “opioids,” defined as “any of various narcotics containing opium or one (1) or more of its natural or synthetic derivatives.” *Id.* at Section 2(e).

15. The emergency rule does not apply to patients with a terminal condition, those enrolled in a health facility licensed under Indiana Code 16-28, those enrolled in a hospice program license under Indiana Code 16-25, and those enrolled in inpatient or outpatient palliative care programs of a hospital licensed under Indiana Code 16-21 or a hospice licensed under Indiana Code 16-25. *Id.* at Section 3(b).

16. Other patients are covered by the emergency rule if they take a specific amount of opioid-containing pills or a morphine equivalent dose of opioids of more than 15 mgs a day for more than three consecutive months. *Id.* at Section 3(c).

17. The covered patients must sign a treatment agreement that includes, among other things, consent to the drug monitoring testing as required by the rule. *Id.* at Section 5(4)(B).

18. Section 8 of the emergency rule, concerning drug testing, provides that:

(a) At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing opioids for a patient shall perform or order a drug monitoring test, which must include a confirmatory test, on the patient.

(b) If the test required under subsection (a) reveals inconsistent medication use patterns or the presence of illicit substances, a review of the current treatment plan shall be required. Documentation of the revised plan and discussion with the patient must be recorded in the patient's chart.

19. The emergency rule does not prohibit law enforcement from gaining access to the test results. In fact, nothing in Indiana law prohibits law enforcement from gaining access to the results.

20. Drug tests fall into two general categories. The first is a presumptive test that establishes whether or not the sample contains classes of drugs and does not necessarily detect lower concentrations of drugs. The second is a confirmatory test which is more specific and expensive and is used to identify specific drugs and confirm a positive and negative test.

21. Initial conducting of a drug monitoring test under section 8(a) is not required for any patient who, prior to January 1, 2015, was already being prescribed the requisite dosage noted in the emergency rule. *Id.* at Sections 3(c), 11(a).

22. The first annual drug monitoring test is not required before January 1, 2015, although a physician may conduct the annual test earlier. *Id.* at Section 11(b).

23. The requirement that the patient sign a treatment agreement that requires, among other things, patient consent to drug monitoring testing, however, is effective December 15, 2013. *Id.* at Sections 11(a), 12.

Facts

24. James Wierciak suffers from a host of health problems including, but not limited to, numerous stints in his heart, diabetes, neuropathy, amputation of one his toes, serious renal problems, and arthritis.

25. His conditions cause him pain.

25. His renal problems limit the medications that he can take such that he cannot take medications that are metabolized through his kidneys.

26. He has had the same physician, an internist, for at least 18 years and has been prescribed vicodin to attempt to manage his pain by his internist.

27. He has been prescribed vicodin for years.

28. Vicodin is a painkiller that is a combination of acetaminophen and hydrocodone. Hydrocodone is an opioid pain medication.

29. Vicodin is used to attempt to ameliorate moderate to severe pain.

30. Mr. Wierciak suffers from moderate to severe pain. Although the vicodin helps he still suffers pain and because of his renal problems he cannot take many other forms of pain medication.

31. Mr. Wierciak has been informed by his physician that because of the dose of vicodin that he is receiving, and the length of time he has received it, he is subject to the terms of the emergency rule.

32. Mr. Wierciak has been informed by his physician that his pain is chronic and that he, therefore, will need to be on opioids for the rest of his life.

33. Mr. Wierciak strongly objects to the requirement that he take drug monitoring tests as he is a law-abiding citizen. He has no objection to blood or urine tests that are medically indicated as determined by his doctor but he vehemently objects to having to agree to be tested as a condition of treatment when that is something that is not medically indicated.

34. Nevertheless, in order to receive medication and treatment from his physician he must sign the treatment agreement mandated by the emergency rule that contains, as one of its terms, his consent to drug monitoring testing.

34. He has not yet signed the patient agreement noted in the emergency rule. However, he has an appointment with his internist later this month and he understands, from reviewing the rule, that he will now be required to sign the agreement as a condition of continued treatment with opioids.

35. Although the emergency rule allows the drug monitoring testing to be deferred to January 1, 2015, it also allows the physician to require the testing earlier.

36. He does not want to sign the consent to required drug monitoring testing as he believes that is a violation of his constitutional rights. However, he and his physician are now subject to

the emergency rule and he therefore now is subject to the regulatory requirement that he sign the patient agreement.

37. Mr. Wierciak is being caused irreparable harm for which there is no adequate remedy at law.

38. At all time defendants have acted under color of state law.

Legal claim

39. The requirement in the emergency rule that patients subject to the rule must sign a consent to drug monitoring tests as a condition of receiving treatment, and then must be drug tested, violates the Fourth Amendment to the United States Constitution.

WHEREFORE, plaintiff requests that this Court:

1. Accept jurisdiction of this case and set it for hearing at the earliest opportunity.
2. Certify this case as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with the class as defined above.
3. Declare that the requirement in the emergency rule that a patient must sign a consent to drug monitoring tests, and must have those tests, as a condition of treatment, violates the Fourth Amendment to the United States Constitution.
4. Enter a preliminary injunction, later to be made permanent,
 - a. voiding any patient consent to drug monitoring testing contained in already executed patient agreements provided for in the emergency rule.
 - b. enjoining the requirement that patients must consent, and obtain, drug monitoring testing as provided in the emergency rule.
5. Award plaintiff his costs and reasonable attorneys' fees pursuant to 42 U.S.C. § 1988.
6. Award plaintiff all other proper relief.

/s/ Kenneth J. Falk

Kenneth J. Falk
No. 6777-49

/s/ Gavin M. Rose

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